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DARBY & DARBY P.C.
805 Third Avenue
New York, New York 10022
212-527-7700

Docket No: 3042/0G956

Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Enclosed please find an application for United States patent as identified below:

Inventor/s (name ALL inventors): James D. MARKS

Title: SYSTEM AND METHOD FOR RECRUITMENT OF CANDIDATES FOR CLINICAL TRIALS WHILE MAINTAINING SECURITY

including the items indicated:

1. Specification and 54 claims: 3 indep.; 51 dep.; _ multiple dep.

2. [**X**] Executed declaration and power of attorney
   [] Unexecuted declaration and power of attorney

3. [] Formal drawings, _ sheets (Figs.)
   [X] Informal drawings, 9 sheets (Figs. 1-4)

4. [X] Assignment for recording to: Body Health Resources Corporation

5. [X] Verified Statement Claiming Small Entity Status

6. [X] Check in amount of $691.00, ($651 filing; $40 recording)
(See attached **Fee Computation Sheet**)

7. [] Preliminary Amendment.

8. [] Please amend the description by inserting the following paragraph after the line containing the title on page 1:
"This patent application claims the priority of U.S. provisional patent application No. 60/, which is incorporated herein by reference."

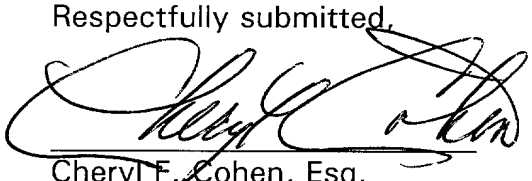
Priority is claimed for this application, corresponding application/s having been filed as follows:

Country:
Number:
Date:

The priority documents [] are enclosed
[] will follow.

Date: April 21, 2000

Respectfully submitted,



Cheryl F. Cohen, Esq.
Reg. No. 40,361
Attorney for Applicant(s)

PATENT FEE COMPUTATION SHEET

	No. of Claims Presented	Extra Claims Previously Paid For	Number of Extra Claims	Rate
Basic Fee				$690.00
Total Claims	54 - 20	- 0 = 34	x $18.00	$612.00
Independent Claims	3 - 3	- 0 = 0	x $78.00	$0.00
Multiple Dependent Claims		- if so, add	$260.00	$0.00

Surcharge for late submission of filing fee and/or declaration ($130.00)	$0.00
SUBTOTAL	$1302.00
[X] Small Entity REDUCTION (Half of Subtotal)	$651.00
Fee for recordation of assignment ($40.00)	$40.00
Charge for filing non-English language application ($130.00)	$0.00
TOTAL	$691.00

M:\3042\0G956\KRJ4128 WPD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application or Patent of: Docket No. 3042/0G956

James D. MARKS

Serial or Patent No: Not Yet Assigned Filed: or Issued: Concurrently Herewith

For: ON-LINE RECRUITMENT OF CLINICAL TRAIL CANDIDATES

VERIFIED STATEMENT CLAIMING SMALL ENTITY STATUS
SMALL BUSINESS CONCERN

I hereby declare that I am

[] the owner of the small business concern identified below:
[] an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN:
ADDRESS OF CONCERN:

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 CFR 121.12 and in 37 CFR 1.9(d), for purposes of paying reduced fees to the United States Patent and Trademark Office, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons.

Definitions: For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention entitled **System and Method for Recruitment of Candidates for Clinical Trials While Maintaining Security**, by inventor(s) James D. MARKS described in

[X] the specification filed herewith
[] application Serial No. , filed
[] Patent No. , issued .

If the rights held by the above identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no

rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 C.F.R. 1.27)

NAME:

ADDRESS:

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

NAME:

ADDRESS:

[] INDIVIDUAL [] SMALL BUSINESS CONCERN [] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 C.F.R. §1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: James D. MARKS
TITLE OF PERSON (IF OTHER THAN OWNER): President/CEO
ADDRESS OF PERSON SIGNING: 101 West 79th Street
New York, NY 10024

SIGNATURE: _____ DATE: 4/21/00

SMALL BUSINESS

REV. (Via PTO) 7/12/89

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D Beck L Beck

Name (Print)Signature

3042/0G956

System and Method for Recruitment of Candidates for Clinical Trials While Maintaining Security

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates generally to a system for recruitment of candidates for clinical trials, and in particular to the recruitment of candidates, such as individuals who are afflicted with AIDS/ HIV positive, who require a certain level of privacy concerning access to their personal and medical information. The invention is also directed to a method of using the same.

Description of Related Art

Before a drug or medical technique is approved for use on the public at large, it is administered to a limited number of patients who participate in clinical trials. It is necessary when selecting individuals to participate in the clinical trials to choose only those individuals who meet particular exclusion and inclusion criteria for a specific trial. Selection of candidates to participate in such clinical trials may depend on factors, such as the gender, age, symptoms, prognosis, and previous medical treatments.

Conventional methods of solicitation, such as newspaper and magazine advertisements have heretofore been widely used to solicit individuals to participate in clinical trials. By way of example, an advertisement may be directed to individuals who suffer from

asthma and are currently on steroids. Individuals who meet the requirements specified in the advertisement are invited to call a particular number or inquire to be considered as a candidate to participate in the clinical trial.

With the advent of the Internet, web sites, such as Koop.com, Americasdoctor.com and Intertrials.com, have electronically implemented the conventional solicitation process for on-line recruitment of candidates for clinical trials. The procedures used by these conventional web sites, however, are not suitable for receiving personally identifiable medical data concerning patients who suffer from diseases, ailments, disorders, and medical conditions, such as HIV/AIDS, that require a certain level of security against potential unwanted dissemination of personal and/or medical information, and the right to remove one's name from a list of volunteers. Not only is the privacy of such data desirable from the point of view of the individual and their family, but legislation and regulations mandate the level of security to be accorded personal and medical information. For example, the federal department of Health and Human Services has recently promulgated regulations concerning the level of security to be accorded transmission of medical records and personal data, and in particular New York legislation requires that prior to dissemination of medical information the individual sign a release form and that an opt out method be available when recruiting candidates for clinical trials. Other countries have recently adopted guidelines, such as the European Union data directive concerning procedural aspects of the dissemination of personal and medical information.

It is therefore desirable to develop a system and method for online recruitment of candidates for clinical trials and research studies that overcomes the aforementioned problems.

Summary of the Invention

The following terms used to describe the invention are defined as follows:

"End user" is an individual that accesses the web site for on-line recruitment of candidates for clinical trials.

"Volunteer" is an end user that visits and registers with the web site to be considered as a potential candidate for a clinical trial.

"Candidate" is a volunteer selected to take part in a clinical trial.

"Web site" is a server application which accepts connections from client programs, such as browsers, that allow a remote end user to access and register as a volunteer for on-line recruitment of candidates for clinical trials.

The terms "clinical trials" and "research studies" are used interchangeably throughout the description and the claims.

It is an object of the present invention to develop an on-line click wrap agreement for the release of medical and personal information by end users prior to volunteering to be considered as a potential candidate for clinical trials. The agreement authorizes the release of the end user's medical and/or personal information to representatives of the clinical trials and research studies for which the volunteer may be considered as a potential candidate. After receiving the end user's consent to the click wrap agreement an electronic survey form is generated by a secure server and displayed at the end user's computer terminal. Responses by the end user to the survey form are kept secure as much as possible while being transmitted from the computer terminal across the network to the server and while stored and accessed only by authorized personnel at the central office.

The invention is directed to a method for using a system for on-line recruitment of candidates for clinical trials in which an end user's consent to an electronic agreement relating to volunteering as a potential candidate for a clinical trial and the release of at least one of medical and personal information is received by a central office.

In addition, the invention relates to a system for on-line recruitment of candidates for clinical trials over a network including a secure server for generating an electronic agreement, and one or more computer terminals on which is displayed the electronic agreement. The computer terminal is used by an end user to provide their consent to the electronic agreement to volunteer as a potential candidate for a clinical trial and release medical and/or personal data. In this configuration the server and computer terminals are connected via a network.

Brief Description of the Drawing

The foregoing and other features of the present invention will be more readily apparent from the following detailed description and drawings of illustrative embodiments of the invention wherein like reference numbers refer to similar elements throughout the several views and in which:

Figure 1 is an exemplary high-level diagram of a secure system for on-line recruitment of candidates for clinical trials in accordance with the present invention;

Figure 2 is an exemplary flow chart of the operating steps of the secure system for on-line recruitment of candidates for clinical trials in accordance with the present invention;

Figures 3a-3f is an exemplary Health Survey form display screen in accordance with the present invention; and

Figure 4 is an exemplary Opt-out display screen in accordance with the present invention.

Detailed Description of the Invention

By way of example, the discussion of the system and method in accordance with the present invention is directed to on-line recruitment of volunteers as potential candidates for clinical trials relating to drugs and/or medical treatment of individuals suffering from AIDS/HIV. It should be noted, however, that the recruitment is also applicable to other diseases, ailments, disorders, and medical conditions, such as infectious diseases, or infertility, in which individuals suffering therefrom are stigmatized and thus, would benefit from the implementation of optimum security measures. In addition, the system is also advantageous in view of recent federal and state laws and regulations that mandate the level of security to be accorded the transmission and dissemination of personal and medical data.

Figure 1 is a high-level diagram of a system or server 100 having a memory device 105. System 100 is connected to a central or main office 110 having a memory device 115. Although the main office 110 is shown in Figure 1 as separate and remote from the system 100, the two devices may be in a single location or unit. System 100 is accessed by multiple computer

terminals 125, 130, 135 connected via a network 120, such as the Internet. While the system and method in accordance with the present invention is described in the context of the Internet or world wide web, it can also be used in other network environments, such as a local area network (LAN), Intranet, wide area network (WAN), or various wireless technology platforms, where the system and software are accessible by both subscribers and end users alike from remote locations. Only three computer terminals are shown, however, any number of computers may be connected to network 120 through known communication interfaces, such as an external or built-in modem (not shown). End users may access the system from any computer terminal throughout the world having appropriate network Internet access and software, such as a web browser. The system 100 uses a secure server, such as Netscape™, using secure socket layer (SSL) protocols or alternative security means. System 100 may be designed so that an end user must employ a web browser that supports SSL. In a preferred embodiment, system 100 notifies the end user if their web browser does not support SSL or if the particular version of the Internet access software installed by the end user falls below a minimum acceptable level of security functionality.

Figure 2 is an exemplary flow chart of the operation of the secure system for on line recruitment of candidates for clinical trials and research studies. The end user visits the web site and sever 100 automatically generates an introductory home page displayed at the user's computer terminal briefly describing the nature of the services being provided at the web site. In a preferred embodiment, the end user is able to access additional information, e.g., publications, concerning some of the pros and cons associated with participating in a clinical trial, to assist the end user in their decision whether or not to register as a volunteer.

In step 210, server 100, in response to the end user selecting or clicking on a button or icon to proceed or continue, generates a Participation Agreement that is displayed at the end user's computer terminal. The agreement may be drafted, as desired, to cover all legal issues, such as the liabilities and duties of each party. By way of example, the Participation Agreement may include one or more provisions directed to (1) the voluntary nature of the information being provided by the volunteer; (2) the disclaimer of any guarantee of information being provided to clinical researchers or labs; (3) duties on the part of the service to take all reasonable measures

to maintain the confidentiality of the data entered by the volunteer; (4) limitations of liability on the part of the service; (5) compensation and ownership rights; (6) independence of the service with respect to the clinical researchers and labs; (7) the volunteer's informed consent upon completing the Health Survey form; (8) authorization by the volunteer to release all data provided in response to the Health Survey form; (9) applicable governing law for disputes which may arise under the contract; and (10) additional provisions directed to laws and regulations in specific states. The end user agrees or consents to be bound by the terms and conditions presented in the Participation Agreement by clicking on an acceptance button or icon before being considered as a possible candidate for a clinical trial or research study.

Upon agreeing or consenting to the terms of the Participation Agreement, for example, by clicking on the acceptance button or icon, in step 220, server 100 produces a Health Survey form display screen at the computer terminal of the end user. Figures 3a-3f is an exemplary Health Survey form display screen requesting that the end user enter personal and/or medical information about themselves. By way of example in Figures 3a-3f, the end user may be asked personal questions such as their age, sex, name, address, telephone number, and medical questions, such as, their health condition status, how long they have been HIV positive, specific test results, medications the end user is currently taking or has taken in the past, infections or complications the end user may have had or currently has. Figure 3 also shows some illustrative examples of the type of responses that may be entered by the end user. For example, the end user may be requested to enter text and/or numerical information in a data entry field, select one or more entries from a list of available options, select one or more entries from a pull down menu, or any combination thereof. The Health Survey form may therefore be designed, as desired, depending on such factors as the nature of the particular disease, ailment, disorder or medical condition to which the research studies and clinical trials are directed. Representatives of a registered clinical trial or research study may adapt the questions presented in the Health survey form in accordance with inclusion or exclusion criteria for their particular study.

In Figure 2, after the end user has responded to all of the questions in the Health Survey form and clicked on a "Submit" button or icon, in step 230, the data entered is

automatically encrypted by the volunteer's web browser software before being transmitted to the server 100. Thus, any potential hackers attempting to intercept the confidential information during transmission between the volunteer's computer terminal and the server 100 will be unable to decipher the data.

Thereafter, in step 240 the encrypted data is transmitted from the end user's computer terminal to the server 100 via network 120. In a preferred embodiment, if the end user has not entered a response to one or more questions, then an error message is displayed with the subject matter of the unanswered questions and prompts the end user to go back to the previous screen to correct these responses.

After agreeing to the Consent Agreement and completing the Health Survey form, to confirm that the information provided in response to the Health Survey will be sent directly to the system or server 100, the volunteer may access a digital certificate procured, for example, by Verisign™, to verify communication between the end user's browser and server 100. Alternatively, a digital certificate may be automatically generated in response to the user completing the Health Survey form.

In steps 250-260 of Figure 2, the encrypted responses to the Health Survey form received at the server 100 are decrypted and stored in memory device 105. The decrypted data stored in memory device 105 is subject to access by potential hackers who gain access to that server to observe the data while in its decipherable state. Server 100 circumvents this potential problem by implementing one or more precautionary measures. In particular, server 100 may be programmed to restrict access to the server to only a minimum number of trusted and screened employees. Security policies and procedures may be implemented to ensure that unauthorized personnel never access the decrypted information received by the server.

In steps 270-280, server 100 processes the volunteer's data responses to the Health Survey, preferably using a specification, such as Common Gateway Interface (CGI) "scripts", to extend the service and capabilities of the web server, and automatically encrypts the processed data using Pretty Good Privacy (PGP) or some other known shareware encryption protocol. Thereafter, in step 290, immediately after encryption, server 100 destroys or purges the

unencrypted volunteer's data stored in memory device 105, which, in turn, is replaced with the encrypted processed data. Encrypted processed data stored in memory device 105 is then transmitted from server 100 to the main or central office 110, in step 300.

At the main or central office 110, access to the volunteer's data is restricted to limited personnel. In step 310, the volunteer's data is stored in encrypted form in memory 115. Thereafter, in step 320, the data stored in memory 115 is retrieved and decrypted only when requested by authorized personnel. Encryption keys are preferably stored on an external memory device, such as a floppy disk, a compact disk, or some other storage device, and kept under surveillance, e.g., under lock and key, to which only authorized employees have access.

At any point in time a volunteer may opt-out by removing their name from the database of volunteers. Figure 4 is an exemplary Opt-Out form display screen. The volunteer is preferably asked to enter their first name, last name, and date of birth. Any information may be requested so long as the particular volunteer to be removed can be properly identified. Additional information may be used to properly identify the volunteer, such as the maiden name of the volunteer's mother. It is contemplated that the most basic information, e.g., the full name and date of birth of the volunteer, may be initially requested and that additional information will be solicited only if the database identifies multiple matches from the database of volunteers. In an alternative embodiment, the volunteer when registering with the service is assigned a unique identification number that may be subsequently entered by the volunteer when requesting to be removed from the list of potential candidates. In this alternative embodiment, if the volunteer could not recall their identification number, other means for identifying the volunteer as discussed above may be employed.

Researchers and lab technicians interested in accessing the database of volunteers to obtain candidates for its clinical trials and/or research studies register with the central office 110. The registration process may be performed on-line by accessing the web site or via some other communication medium, such as by filling out a printed registration form. By way of example, the registration form may request the name of an authorized officer conducting the research, the subject matter being researched, the medical professionals associated with the

research, and the criteria used in the selection of candidates as well as the number of candidates being sought. The completed registration form is forwarded to the central office. In a preferred embodiment of the invention, the central office verifies the credentials and legitimacy of the clinical trial and research study being conducted before establishing an affiliation. Once initial approval is provided, a representative on behalf of the clinical trial or research study must enter into an agreement to be bound by the rules set forth by the central office concerning the prevention against unwanted dissemination of the personal and medical records of its volunteers. A registered clinical researcher or lab may modify the information requested in the Health Survey form based on their own particular needs.

After a volunteer has been selected as a potential candidate for a clinical trial or research study, they are contacted directly by a representative of the clinical trial or research study. All communication is conducted directly between the two parties, without intervention by the central office. In an alternative embodiment, direct contact between a representative on behalf of the clinical trial or research lab and the volunteer is not initiated until the central office first contacts the volunteer and confirms that they still want to be considered as a potential candidate for the particular clinical trial or research study. After confirming that the volunteer stills wishes to be considered as a potential candidate for the particular clinical trial or research study, all communication thereafter would be directly between a representative of the particular clinical trial or research study and the volunteer.

It is desirable to develop a comprehensive security system. Accordingly, additional safeguards are contemplated and within the intended scope of the invention including the use of firewalls or other known security measures. The present invention has been described for recruitment of volunteers as potential candidates for clinical trials or research studies concerning a single disease, e.g., HIV/AIDS. It is, however, contemplated that the server may initially generate a display screen requesting the user to select from a number of diseases, ailments, disorders or medical conditions in which to participate as a volunteer. In this situation the Health Survey form may be modified depending on the particular disease, ailment, disorder or medical condition for which the individual is volunteering.

In the operation of the on-line recruitment system as described above, the volunteer must agree to opt in or opt out of all registered clinical trials or research studies. Alternatively, the system may be adapted so that the server 100 displays a list of all registered clinical trials and research studies that are currently recruiting candidates from which the volunteer may select or target one or more registered clinical researchers/labs that they wish to be listed as a volunteer and be considered as a potential candidate. The volunteer's personal and medical information will only be accessible by those clinical trials and research studies that have been selected by the volunteer.

Thus, while there have been shown, described, and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions, substitutions, and changes in the form and details of the devices illustrated, and in their operation, may be made by those skilled in the art without departing from the spirit and scope of the invention. For example, it is expressly intended that all combinations of those elements and/or steps which perform substantially the same function, in substantially the same way, to achieve the same results are within the scope of the invention. Substitutions of elements from one described embodiment to another are also fully intended and contemplated. It is also to be understood that the drawings are not necessarily drawn to scale, but that they are merely conceptual in nature. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

Claims

What is claimed is:

1. A method for using a system for on-line recruitment of candidates for clinical trials comprising the step of:

receiving over a network from a computer terminal an end user's on-line consent to an electronic agreement relating to volunteering as a potential candidate for a clinical trial and the release of at least one of medical and personal information.

2. A method in accordance with claim 1, wherein the electronic agreement is a click wrap consent agreement.

3. A method in accordance with claim 1, further comprising generating an electronic survey form to be displayed at the computer terminal, in response to receipt of the end user's consent to the electronic agreement.

4. A method in accordance with claim 3, wherein the electronic survey form comprises at least one of personal and medical related questions.

5. A method in accordance with claim 3, further comprising encrypting data entered by the user in response to the survey form.

6. A method in accordance with claim 5, further comprising transmitting the encrypted data to a secure server via the network.

7. A method in accordance with claim 6, wherein the network is one of an Internet,

world wide web, intranet, local area network, wide area network, and wireless communication network.

8. A method in accordance with claim 6, further comprising decrypting the data received at said secure server.

9. A method in accordance with claim 8, further comprising storing the decrypted data in a first memory device associated with said secure server.

10. A method in accordance with claim 9, further comprising processing the decrypted data retrieved from the first memory device.

11. A method in accordance with claim 10, further comprising encrypting the processed data.

12. A method in accordance with claim 11, further comprising replacing the decrypted data in the first memory device with the encrypted processed data.

13. A method in accordance with claim 12, further comprising transmitting the encrypted processed data from said secure server to a central office.

14. A method in accordance with claim 13, further comprising storing the encrypted processed data in a second memory device associated with said central office.

15. A method in accordance with claim 14, further comprising the steps of:

in response to a request from an authorized individual, retrieving the encrypted processed data from the second memory device; and

decrypting the retrieved encrypted processed data from the second memory device.

16. A method in accordance with claim 1, further comprising generating a certificate to verify transmission between the end user and secure server.

17. A method in accordance with claim 3, wherein the computer terminal employs a web browser capable of supporting a secure socket layer protocol.

18. A method in accordance with claim 8, further comprising ensuring that decrypted data stored at said secure server is not accessed by unauthorized personnel.

19. A method in accordance with claim 18, wherein said ensuring step comprises at least one of limiting access to said secure server to a minimum number of authorized personnel, identifying as authorized personnel only trustworthy employees, and devising and implementing procedures to ensure that only authorized personnel gain access to the decrypted data.

20. A method in accordance with claim 1, further comprising generating using said secure server an electronic opt-out form to be displayed on the computer terminal to remove the end user's name from a list of volunteers as possible candidates for clinical trials.

21. A method in accordance with claim 1, wherein the electronic agreement satisfies all federal, state, and local rules, ordinances and regulations.

22. A method in accordance with claim 11, wherein said secure server encrypts the data based on a shareware encryption protocol.

23. A method in accordance with claim 27, wherein said shareware encryption protocol is Pretty Good Privacy.

24. A method in accordance with claim 15, wherein said decryption of the retrieved encrypted data from the second memory device is performed using encryption keys stored on a disk kept under physical surveillance.

25. A method for using a system for on-line recruitment of candidates for clinical trials comprising the step of:

providing on-line consent by an end user at a computer terminal to an electronic agreement relating to volunteering as a potential candidate for a clinical trial and release of at least one of medical and personal information.

26. A method in accordance with claim 25, wherein the electronic agreement is a click wrap consent agreement.

27. A method in accordance with claim 25, further comprising, after providing consent to the electronic agreement, responding at the end user's computer terminal to information solicited in an electronic survey form.

28. A method in accordance with claim 27, wherein the electronic survey form comprises at least one of personal and medical related questions.

29. A method in accordance with claim 27, wherein the electronic survey form is received by the user's computer terminal via a network.

30. A method in accordance with claim 29, wherein the network is one of an Internet, world wide web, Intranet, local area network, wide area network, and wireless communications network.

31. A system for on-line recruitment of candidates for clinical trials over a network

comprising:

a secure server generating an electronic agreement; and

at least one computer terminal on which is displayed the electronic agreement, said at least one computer terminal used by an end user to provide consent to said electronic agreement to volunteer as a potential candidate for a clinical trial and release at least one of medical and personal data, said secure server and said at least one computer terminal being connected via the network.

32. A system in accordance with claim 31, wherein said secure server, in response to the end user consenting to the electronic agreement, generates an electronic survey form at said at least one computer terminal.

33. A system in accordance with claim 32, wherein the electronic survey form comprises at least one of personal and medical related questions.

34. A system in accordance with claim 33, wherein said at least one computer terminal is used to enter at least one of personal and medical data in response to the questions in the electronic survey form.

35. A system in accordance with claim 34, wherein said at least one computer terminal includes web browser software for encrypting the response data entered at said at least one computer terminal.

36. A system in accordance with claim 35, wherein said encrypted response data is received by said secure server from said at least one computer terminal via the network.

37. A system in accordance with claim 36, wherein said secure server decrypts the encrypted response data.

38. A system in accordance with claim 37, wherein said secure server includes a first memory device for storing the decrypted response data.

39. A system in accordance with claim 38, wherein said secure server processes the decrypted response data retrieved from said first memory device.

40. A system in accordance with claim 39, wherein said secure server encrypts the processed data.

41. A system in accordance with claim 40, wherein said secure server replaces the decrypted response data in said first memory device with said encrypted processed data.

42. A system in accordance with claim 41, further comprising a central office connected to said secure server.

43. A system in accordance with claim 42, wherein said secure server and central office are a single device at the same location.

44. A system in accordance with claim 43, wherein said central office receives the encrypted processed data transmitted from said secure server.

45. A system in accordance with claim 44. wherein said central office includes a second memory device for storing the encrypted processed data.

46. A system in accordance with claim 45, wherein said central office, in response to a request from an authorized individual, retrieves and decrypts the encrypted processed data from said second memory device.

47. A system in accordance with claim 35, wherein said web browser software is capable of supporting a secure socket layer protocol.

48. A system in accordance with claim 46, wherein said secure server ensures that the decrypted processed data is not accessed by unauthorized personnel.

49. A system in accordance with claim 48, wherein said secure server ensures that the decrypted processed data is not accessed by unauthorized personnel by limiting access to said secure server to a minimum number of authorized personnel.

50. A system in accordance with claim 31, wherein said secure server generates an electronic opt-out form on said at least one computer terminal to remove a volunteer's name as a possible candidate for clinical trials.

51. A system in accordance with claim 31, wherein said electronic agreement satisfies all federal, state and local laws and regulations concerning dissemination of medical, health and personal information.

52. A system in accordance with claim 31, wherein said network is one of an Internet, world wide web, Intranet, local area network, wide area network, and wireless communication network.

53. A method in accordance with claim 1, further comprising the step of receiving an end user's section of at least one from a list of a plurality of possible clinical trials to volunteer as a potential candidate.

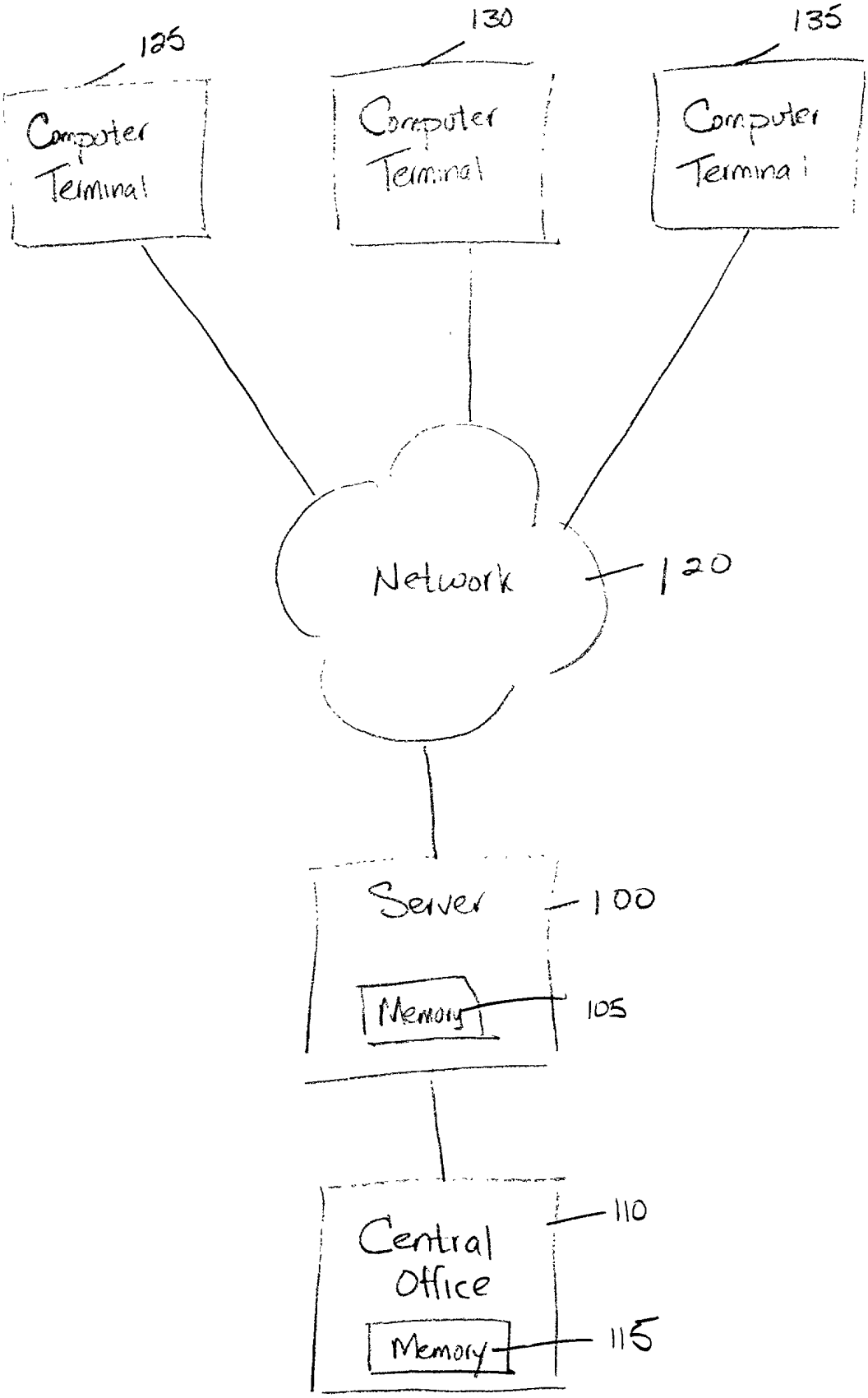
54. A method in accordance with claim 53, further comprising the step of permitting access of at least one of medical and personal information only by representatives of the

selected clinical trials.

Abstract

An on-line click wrap electronic agreement that a user must agree to prior to being registered as a volunteer and considered as a potential candidate in a clinical trial or research study. The agreement authorizes the release of the end user's medical and/or personal information to representatives of the clinical trials and research studies for which the volunteer may be considered as a potential candidate. After receiving the end user's consent to the click wrap agreement an electronic survey form is generated by a secure server and displayed at the end user's computer terminal. Responses by the end user to the survey form are kept secure as much as possible while being transmitted from the computer terminal across the network to the server and while stored and accessed only by authorized personnel at the central office.

FIG. 1


125
Computer Terminal
130
Computer Terminal
135
Computer Terminal
Network
120
Server
100
Memory
105
Central Office
110
Memory
115

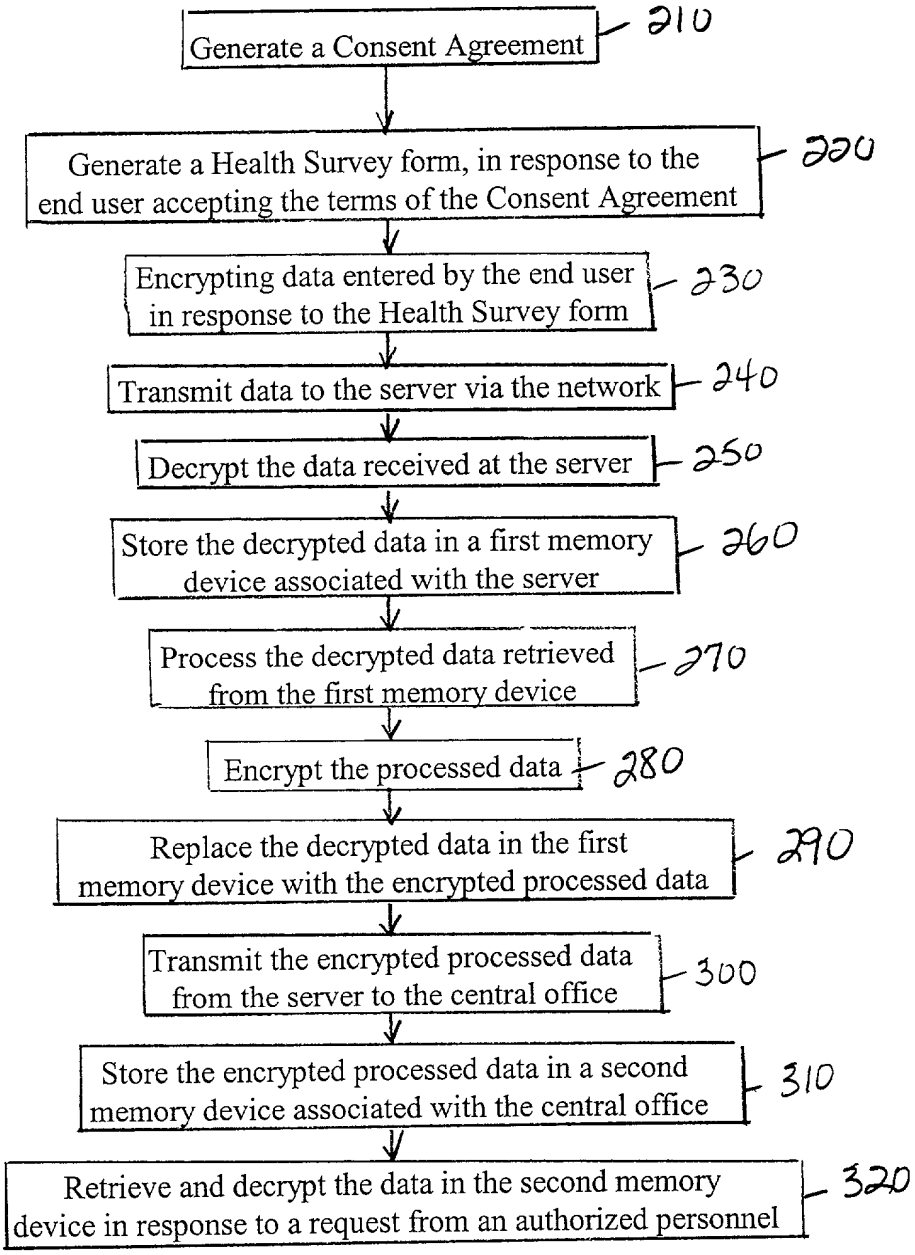

Generate a Consent Agreement
210
Generate a Health Survey form, in response to the end user accepting the terms of the Consent Agreement
220
Encrypting data entered by the end user in response to the Health Survey form
230
Transmit data to the server via the network
240
Decrypt the data received at the server
250
Store the decrypted data in a first memory device associated with the server
260
Process the decrypted data retrieved from the first memory device
270
Encrypt the processed data
280
Replace the decrypted data in the first memory device with the encrypted processed data
290
Transmit the encrypted processed data from the server to the central office
300
Store the encrypted processed data in a second memory device associated with the central office
310
Retrieve and decrypt the data in the second memory device in response to a request from an authorized personnel
320

FIG. 2

Health Survey

1. How old are you? ___ years old

2. Please enter your sex:

○ I am male
○ I am female

3. How would you characterize your health?

○ excellent
○ good
○ fair
○ poor

4. How long do you think you have been infected? (Note: The Health Survey focuses on people who are HIV-positive.)

○ less than one year
○ one to two years
○ two to four years
○ four to six years
○ six to eight years
○ more than eight years
○ more than 11 years
○ I don't know

5. Would you be willing to participate as a subject in a medical research project?

○ yes
○ no

6. What was your last viral load count?

_____

○ I don't know

FIG 3a

7. What was your last T-Cell count?

- ○ under 100
- ○ 100 to 200
- ○ 200 to 300
- ○ 300 to 400
- ○ 400 to 500
- ○ 500 to 600
- ○ over 600
- ○ I don't know

8. Which HIV antiviral medications are you currently taking? Select as many as apply:

- ☐ 3TC (Lamivudine)
- ☐ Abacavir (Ziagen, formerly 1592U89)
- ☐ Amprenavir (Agenerase)
- ☐ AZT (Zidovudine, ZDV)
- ☐ Combivir (AZT plus 3TC)
- ☐ d4T (Stavudine)
- ☐ ddC (Hivid)
- ☐ ddI (Didanosine)
- ☐ Delavirdine (Rescriptor)
- ☐ Efavirenz (Sustiva, formerly DMP-266)
- ☐ Loviride
- ☐ Nevirapine (Viramune)
- ☐ Indinavir (Crixivan, MK-639)
- ☐ Nelfinavir (Viracept)
- ☐ Ritonavir (Norvir)
- ☐ Saquinavir (Invirase, Fortovase)
- ☐ Other anti-HIV medications (please specify; note that more medications are listed in Question 10)

- ☐ I don't know
- ☐ I am currently not taking any medications

FIG. 36

9. Which HIV antiviral medications have you taken in the past? Select as many as apply:

- ☐ 3TC (Lamivudine)
- ☐ Abacavir (Ziagen, formerly 1592U89)
- ☐ Amprenavir (Agenerase)
- ☐ AZT (Zidovudine, ZDV)
- ☐ Combivir (AZT plus 3TC)
- ☐ d4T (Stavudine)
- ☐ ddC (Hivid)
- ☐ ddI (Didanosine)
- ☐ Delavirdine (Rescriptor)
- ☐ Efavirenz (Sustiva, formerly DMP-266)
- ☐ Loviride
- ☐ Nevirapine (Viramune)
- ☐ Indinavir (Crixivan, MK-639)
- ☐ Nelfinavir (Viracept)
- ☐ Ritonavir (Norvir)
- ☐ Saquinavir (Invirase, Fortovase)
- ☐ Other (please specify)

- ☐ I don't know
- ☐ I have never taken any medications for HIV

FIG. 3C

10. What additional medications are you currently taking? Select as many as apply:

- ☐ Acyclovir (Zovirax)
- ☐ Adefovir (Preveon)
- ☐ Amphotericin B (Fungizone)
- ☐ Atovaquone (Mepron)
- ☐ Azithromycin (Zithromax)
- ☐ Bactrim (TMP/SMX)
- ☐ Cidofovir (Vistide)
- ☐ Ciprofloxacin (Cipro)
- ☐ Clarithromycin (Biaxin)
- ☐ Clindamycin (Cleocin)
- ☐ Clofazimine (Lamprene)
- ☐ Cycloserine (Seromycin)
- ☐ Dapsone
- ☐ Emivirine (MKC-442)
- ☐ Ethambutol
- ☐ Fluconazole (Diflucan)
- ☐ Flucytosine (Ancobon)
- ☐ Fomivirsen (ISIS 2922)
- ☐ Foscarnet (Foscavir)
- ☐ Ganciclovir (Cytovene)
- ☐ Inderal
- ☐ Isoniazid
- ☐ Itraconazole (Sporanox)
- ☐ Leucovorin
- ☐ Pentamidine (aerosolized)
- ☐ Prozac
- ☐ Pyrazinamide
- ☐ Pyrimethamine (Daraprim, Fansidar)
- ☐ Rifabutin (Mycobutin)
- ☐ Rifampin (Rifadin)
- ☐ Rimantadine
- ☐ Sparfloxacin
- ☐ Sulfadiazine
- ☐ Other (please list all other medications you are taking)

_____

- ☐ I am not taking any additional medications

FIG. 3d

11. Have you ever been diagnosed with any of the following infections or complications? Select as many as apply:

- ☐ Anemia
- ☐ Cancer
- ☐ Candidiasis
- ☐ Cryptococcosis
- ☐ Cryptosporidiosis
- ☐ Cytomegalovirus (CMV)
- ☐ Hepatitis
- ☐ Herpes
- ☐ Kaposi's Sarcoma (KS)
- ☐ Microsporidiosis
- ☐ Mycobacterium avium Complex (MAC)
- ☐ Neuropathy
- ☐ AIDS Dementia
- ☐ PML (Progressive Multifocal Leukoencephalopathy)
- ☐ Other Neurological/Neurocognitive Complications
- ☐ Non-Hodgkins Lymphoma
- ☐ Oral and Esophageal Thrush
- ☐ Pneumocystis carinii Pneumonia (PCP)
- ☐ Sinusitis
- ☐ Toxoplasmosis
- ☐ Tuberculosis
- ☐ Wasting
- ☐ Other (please specify)

- ☐ I have never been diagnosed with any infection or complication of HIV

FIG. 3e

12. Can we contact you by e-mail about participating in a clinical research project?

○ No
○ Yes

If yes, please provide your e-mail address:
_____

13. May we phone you? (Note: To be contacted to participate, you must provide an e-mail address or phone number)

○ No
○ Yes

If yes, please provide your phone number:
area code ____ number _____

14. Please provide your name and place of residence.

Last name:
_____

First name:
_____

Place of residence:
City _____ State ---- ▼ Zip Code _____

15. In order for us to identify you properly, please give us your birthdate:

Month: _____ Day: ____ Year: ____

Thank you for taking the time to take this survey. Please note that no one will contact you unless or until there is an appropriate request from a lab or researcher.

Submit

FIG. 3f

Please fill in the following form if you'd like to remove your name from our list of volunteers. Please be as accurate as possible so that we will be able to locate your original submission.

_____ First Name

_____ Last Name

Birthdate:

Month: _____ Day: ___ Year: ____

Submit

FIG. 4

Docket No.:3042/0G956

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I declare that:

1. The information given herein is true, and I believe that I am the original, first and sole inventor (if only one name is listed below), or a joint inventor (if plural inventors are named below), of the invention entitled:

System and Method for Recruitment of Candidates for Clinical Trials While Maintaining Security

which is described and claimed in:

[X] the attached specification or

[] the specification in application
Serial No. ,
Filed:

1. I acknowledge my duty to disclose information of which I am aware which is material to patentability in accordance with 37 C.F.R. §1.56, including such material information which occurred between the filing date of said earlier application and the filing date of this application.

2. I have reviewed and understand the contents of the specification, including the claims, as amended by any amendment specifically referred to herein.

3. As to the subject matter of this application which is common to said earlier application I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof or patented or described in any printed publication in any country before my or our invention thereof, or more than one year prior to said earlier application or in public use or on sale in the United States of America more than one year prior to said earlier application; said common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of said earlier application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to said earlier application. As to the subject matter of this application which is common to said earlier application, I hereby claim the priority benefits under 35 U.S.C. 119 of any

application(s) for patent or inventor's certificate listed below. All applications for patent or inventor's certificate on this invention filed by me or my legal representatives or assigns prior to the application(s) of which priority is claimed as to the common subject matter are also identified below.

PRIOR APPLICATION(S), IF ANY, OF WHICH PRIORITY IS CLAIMED

COUNTRY	APPLICATION NO.	DATE OF FILING

ALL FOREIGN APPLICATIONS, IF ANY, FILED PRIOR TO THE APPLICATION(S) OF WHICH PRIORITY IS CLAIMED

COUNTRY	APPLICATION NO.	DATE OF FILING

4. As to the new subject matter of the present application which is not common to said earlier application I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof or patented or described in a printed publication in any country before my or our invention thereof or more than one year prior to the date of this application, or in public use or on sale in the United States of America more than one year prior to the date of the present application, and said matter has not been patented or made the subject of an inventor's certificate in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to the date of this application. As to the new subject matter of the present application which is not common to said earlier application, I hereby claim the priority benefits under 35 U.S.C. 119 of any application(s) for patent or inventor's certificate listed below. All applications for patent or inventor's certificate on this

invention filed by me or my legal representatives or assigns prior to the application(s) of which priority is claimed for the new subject matter are also identified below.

PRIOR APPLICATION(S), IF ANY, OF WHICH PRIORITY IS CLAIMED

COUNTRY	APPLICATION NO.	DATE OF FILING

ALL FOREIGN APPLICATIONS, IF ANY, FILED PRIOR TO THE APPLICATION(S) OF WHICH PRIORITY IS CLAIMED

COUNTRY	APPLICATION NO.	DATE OF FILING

POWER OF ATTORNEY:

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: Gordon D. Coplein #19,165, William F. Dudine, Jr. #20,568, Michael J. Sweed er #19,937, S. Peter Ludwig #25,351, Paul Fields #20,788, Marc S. Gross #19,614, Harold E. Wurst #22,193, Joseph S. Lerch #26,936, Melvin C. Garner #26,272, Ethan Horwitz #27,646, Beverly B. Goodwin #26,612, Anita C. Gagnon #26,714, Martin E. Goldstein #20,868, Bart J. Lauren #19,407, Henry Sternberg #22,408, Robert A. Green #28,301, Peter C. Schechter #31,552, Robert Schaffer #31,196, Robert C. Sullivan, Jr. #30,499, Ira J. Levy #35,567, Joseph R. Robinson #33,448, Cheryl F. Cohen, #40,361

all of the firm of DARBY & DARBY P.C., 805 Third Avenue, New York, NY 10022

SEND CORRESPONDENCE TO:

DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

DIRECT TELEPHONE CALLS TO: Cheryl F. Cohen, Esq.

212-527-7700

Docket No. 3042/0G959

FULL NAME AND RESIDENCE OF INVENTOR 1

LAST NAME: MARKS FIRST NAME: JAMES MIDDLE NAME: D.

CITY: NEW YORK STATE OR FOREIGN COUNTRY: NEW YORK COUNTRY OF CITIZENSHIP: USA

POST OFFICE ADDRESS: 101 WEST 79TH STREET CITY: NEW YORK STATE OR COUNTRY: NEW YORK

ZIP CODE: 10024

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

James D. MARKS

Date: 4/21/01